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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/335,461	11/07/1994	RUTH A. GIERSET		8495

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EXAMINER	
LOW, CHRISTOPHER S F	
ART UNIT	**PAPER NUMBER**
1653	31

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/335,461	Applicant(s) GIERSET ET AL.	
	Examiner Christopher S. F. Low	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 Oct 2001 and the Board decision* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,8-15,17-20 and 23* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed. 1, 2, 4 – 20 and 23

6)☐ Claim(s) *1,2,4,5,8-15,17-20 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12 and 2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

In view of the decision by the United States Patent And Trademark Office Board Of Patent Appeals And Interferences and the submission of the information disclosure statement (USPTO mailroom date of 23 Oct 2001), prosecution is reopened.

Claims 1, 2, and 4-23 were on appeal and are currently pending. The following ground(s) of objection and rejection are applicable to the pending claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Rejection(s) under 35 U.S.C. 102

Claims 1, 2, 4, 5, 8-15, 17-20 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Roth *et al.* (US 6069134 or 5747469 (equivalent to the '134 patent)). The patent disclosed and claimed claim 1 of the instant application. See for example, patented claim 3 among others. The patent teaches delivering genetic material encoding the p53 protein, expressing same (which enhances the sensitivity to the cell to the tumor therapy). Note also the teaching at column 2 regarding the issue of tumor cells with defective genetic material encoding p53. Thus, claims 1 and 2 are anticipated. As to present claim 4, the patent teaches and claims (claim 10-13) radiation as part of the therapy (note that microwave irradiation produces heat which is the same as hyperthermia - excess heat, higher temperature of present application claim 8), that chemotherapy (claims 14+) is part of the therapy. See also the paragraph bridging columns 4-5 of the patent.

Of note is that application claim 9 recites a list of cell types and tissues. The patent claim 29+ recites cell types of application claim 9 (e.g., lymphoma cells, lung carcinoma cells, sarcoma cells). As to application claim 10, the '134 patent teaches and claims the delivery of the gene is via vector (see, e. g., claim 29+) such as an adenoviral vector, adeno-associated vector, herpes simplex based vector, retroviral based vector. The genetic material encoding p53 would have been expected to have been coupled to the virus capsid or particle in a recombinant viruses (column 3) or a liposome (patent claim 44), a polylysine glycoprotein carrier complex (patent claim 45) which also considered to be a ligand.

Claims 17-20 and 23 recite routes of administration by direct, intraarterial, intracavitary, and intravenous infusion and are anticipated by the patent teachings (see e.g., paragraph bridging columns 7 and 8, column 12, lines 52+ as to intraperitoneal (i. e., intracavitary)) and the patent claims 54+. Note that unless specifically differentiated by differences in the process results,

direct, intraarterial, intracavitary, and intravenous infusion are considered as anticipated variations in intravenous administration. See also example 6 regarding intratracheal instillation wherein some degree of aerosolization is anticipated. Thus, the claims are anticipated by the reference.

Rejection(s) under 35 U.S.C. 103

Claims 1, 2, 4-15, 17-20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth *et al.* (US 6069134 or 5747469 (equivalent to the '134 patent)) taken with Moossa *et al.* (Comp. Text. Oncol., vol. 1 and 2). Roth is newly cited and Moosa *et al.* is of record.

Roth *et al.* is applied here as discussed above. As discussed above, the reference combines genetic therapies with conventional drug therapies described in Moosa *et al.* which would have been obvious to use because Roth *et al.* teaches use of same in connection with genetic therapy. Thus, one of ordinary skill would have known and used radiation therapy (as for example Moossa *et al.* at pages 477, 1138, 1140, and 1170), chemotherapy (as for example Moossa *et al.* at pages 527-536, 565-568, 1098, 1140, and 1572), biological therapy (as for example Moossa *et al.* at pages 607-612 using biological response modifiers), cryotherapy (as for example Moossa *et al.* at pages 1098, 1170, 1329, 1368, and 1569-1570), and hyperthermia (as for example Moossa *et al.* at page 1139-1149) are known treatment methods, have been successfully used, and are routine for one of ordinary skill in the art to have used in treating cancers either as single methods or as combined methods in various combinations as well as to have used routine methods for delivery of the therapeutic agent (as for example via an artery (page 590) or a (page 591) body cavity or by IV as for example indicated at page 592) and would have resulted in the process wherein a DNA encoding a tumor sensitizing product would have been delivered to an afflicted individual along with routine known and established appropriate therapies (radiation therapy, chemotherapy, biological therapy, cryotherapy, and hyperthermia therapy in one or more combinations) for treatment of cancers. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

Claims 1, 2, 4-15, 17-20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 6410010) taken with Moossa *et al.* (Comp. Text. Oncol., vol. 1 and 2). Zhang *et al.* is newly cited and Moosa *et al.* is of record.

Zhang *et al.* disclose administering vectors that restore wildtype p53 function (see column 3, line 25+) as a cancer therapy in cells having a mutant or aberrant p53 gene as effective methods of cancer therapy (column 5, lines 15+ as well as column 13 and 14, lines 2+ and 3+ respectively) and where palliative therapy for the patient would have been expected to have been included since (column 16, lines 29+) would indicate (line 57+) inclusion of other palliative therapies. Insofar as the patent suggests other palliative therapies, one of ordinary skill would have known and used radiation therapy (as for example Moossa *et al.* at pages 477, 1138, 1140, and 1170), chemotherapy (as for example Moossa *et al.* at pages 527-536, 565-568, 1098, 1140, and 1572), biological therapy

(as for example Moossa *et al.* at pages 607-612 using biological response modifiers), cryotherapy (as for example Moossa *et al.* at pages 1098, 1170, 1329, 1368, and 1569-1570), and hyperthermia (as for example Moossa *et al.* at page 1139-1149) are known treatment methods, have been successfully used, and are routine for one of ordinary skill in the art to have used in treating cancers either as single methods or as combined methods in various combinations as well as to have used routine methods for delivery of the therapeutic agent (as for example via an artery (page 590) or a (page 591) body cavity or by IV as for example indicated at page 592) and would have resulted in the process wherein a DNA encoding a tumor sensitizing product would have been delivered to an afflicted individual along with routine known and established appropriate therapies (radiation therapy, chemotherapy, biological therapy, cryotherapy, and hyperthermia therapy in one or more combinations) for treatment of cancers and would (Zhang *et al.*, column 16) have been expected to have increased the therapeutic effect of the treatment based on at least the longer period of time the patient would have been expected to have remained alive. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious

Claim 16 is rejected under 35 U.S.C. 103 as being unpatentable over Roth *et al.* (US 6069134 or 5747469 (equivalent to the '134 patent)) taken with Moossa *et al.* (Comp. Text. Oncol., vol. 1 and 2) as applied to claims 1, 2, 4-15, 17-20 and 23 above and further in view of Wu *et al.* (US '320); or, Zhang et al. (US 6410010) taken with Moossa *et al.* (Comp. Text. Oncol., vol. 1 and 2) as applied to claims 1, 2, 4-15, 17-20 and 23 above and further in view of Wu *et al.* Roth *et al.* and Zhang *et al.* are newly cited and the latter two references are of record.

Roth *et al.* (US 6069134) taken with Moossa *et al.* (Comp. Text. Oncol., vol. 1 and 2); and, Zhang et al. (US 6410010) taken with Moossa *et al.* are applied as indicated above and where Roth et al. on the one hand and Zhang et al. on the other hand both teach various vectors and conjugation and/or encapsulation of the vectors, Wu *et al.* disclose a process for *in vivo* delivery (as for example intravenous injection, i.e., a direct injection wherein injection into an artery is an obvious variation of injection into a vein) of DNA to a target cell (see for example column 11, and the abstract as to polylysine) using a complex of asialoglycoprotein to hepatoma cells and for replacement of "defective genes" such as the DNA encoding p53. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

No claims are allowed.

CSFL
1 Jul 2002

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